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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,690	01/09/2001	Orville G. Kolterman	030639.0066.UTL	4666

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EXAMINER	
JIANG, DONG	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 09/756,690	Applicant(s) KOLTERMAN ET AL.	
	Examiner Dong Jiang	Art Unit 1646	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 02 August 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *02 September 2005*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-15, 24-37 and 41*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER

Continuation of 11. does NOT place the application in condition for allowance because: Claims 1-14, 24-36 and 41 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Karpe et al. (Metabolism, 1999, 48:301-307), and in view of Beeley et al. (WO 98/30231), and Beers et al. (the Merck Manual, 1999, 17th edition, pages 200 and 2550), for the reasons set forth in the previous Office Actions mailed on 17 November 2004, and 06 June 2005.

Applicants argue, in the response filed on 02 August 2005, that the discussions of the lowering of plasma lipids in the Beeley reference are in the context of a reduction in food intake, and the reference does not teach or suggest the identification of a subject having elevated postprandial triglyceride levels and the ability of exendins to specifically lower triglycerides; that the Beers reference does not discuss the use of exendins in the reduction of triglycerides; that the Karpe reference does not remedy the deficiencies of Beeley and Beers; and the examiner has not met his burden of establishing a prima facie obviousness case. Applicants argument has been fully considered, but is not deemed persuasive because the key teachings in the Beeley reference are that exendins can lower plasma lipid (comprising mainly triglyceride and cholesterol), and therefore, exendins would be expected to lower plasma lipid in patients with elevated plasma lipid, such as those with heart disease or obesity, and it is less relevant in what context of a condition exendins lower plasma lipid in Beerley's teaching. With respect to the patient population, as discussed in the Karpe reference, patients with elevated postprandial triglyceride levels are at the risk of developing coronary heart disease. Karpe's patients are certainly identified as subjects "having elevated postprandial triglyceride levels", and are in need of lowering triglyceride levels, and thus, read on the limitation in the present claims ("identifying a subject having elevated postprandial triglyceride levels").

With respect to the newly added limitation "wherein said subject's postprandial triglyceride levels are lowered", it completes the method steps, however, such would be an inherent property of the method suggested by the combined prior art references because there is no difference in the active ingredient administered, the method steps, and the patient population between the method of the present invention and that suggested by the combination teachings of the cited references.

Claims 15 and 37 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Karpe et al. (Metabolism, 1999, 48:301-307), Beeley et al. (WO 98/30231), and Beers et al. (the Merck Manual, 1999, 17th edition, pages 200 and 2550), as applied to claims 1-14, 24-36 and 41 above, and further in view of Wagle et al., US 6,326,396 B1, for the reasons set forth in the previous Office Actions mailed on 17 November 2004, and 06 June 2005, and for the reasons above.

Finally, with respect to the Kolterman reference submitted and specifically pointed out by applicants, although it was listed in IDS (PTO-1449) filed on 24 May 2001, a copy of the reference was not provided. Therefore, it was not considered by the examiner at the time when the first Office Action on merit was prepared, which was indicated in the returning PTO-1449 by the examiner. Such a copy had not been forwarded by applicants during the prosecution (with three additional responses). Thus, the instant submission of the Kolterman reference is not timely, and would require further consideration. Therefore, the Kolterman reference has not been considered.